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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,770	06/25/2003	Gerhard Hoefle	45371	2265

7590 04/02/2004

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EXAMINER

SHAMEEM, GOLAM M

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/602,770		HOEFLE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Golam M M Shameem		1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17, 18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23 is/are allowed.
- 6) ☒ Claim(s) 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/077,055.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Priority***

This application is a divisional of 09/836,134 04/16/2001 which claims benefit for foreign priority under 35 U.S.C. § 119 (a)-(d) to Germany 195 42 986.9 11/17/1995 is acknowledged.

### ***Status of Claims***

Claims 17-18 and 21-25 are pending in the application. Receipt is acknowledged of amendment / response filed on February 05, 2004 and that has been entered. Claims 1-16 and 19-20 have been canceled. Claims 21-25 have been rewritten/added.

Claims 17-18 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### ***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected Group II, drawn to a compound and composition of the formula, and the elected compound 4a disclosed in Example 7 on pages 14 of the specification (Remarks, page 9) with traverse is acknowledged. The traversal is on the ground(s) that all the pending claims should be rejoined and examined with the elected Group II because "the election is not appropriate" (Remarks, page10) and therefore, the search and examination of each of the claims of Groups I-III should be possible without imposing a serious burden upon the Examiner. Since the composition claims 24-25 commensurate with the scope of the elected compound, the Examiner agrees to rejoin and examine composition claims with the elected invention (claims 20-25). Therefore, this ground of traversal is rendered moot.

The Examiner respectfully disagrees with the Applicants other arguments because the products of groups I-II (compounds/compositions) and III (process) differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. Inventions are independent if it can be shown that they are not disclosed as capable of use together, having different modes of operation, different functions or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions are drawn to distinct processes of preparing different compounds, requiring different search strategies because of the different reactive steps and conditions involved in each group and to search all the above groups in a single application would be an undue burden on the Examiner.

Because of the plethora of classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

***Claim Rejections – 35 U.S.C. § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-25 are rejected under 35 U.S.C. § 101 because claims lack patentable utility.

These claims recite a pharmaceutical composition that may especially demonstrate cytotoxic

Art Unit: 1626

activities and/or cause immuno-suppression and /or used to be combat malignant tumors (specification, page 7). However the claims do not recite any effective amounts, thus these claims do not read on an amount that would be effective to combat malignant tumors and an amount that would not be toxic to the patient, therefore, a concern as to the utility of the composition comes into the question. Amending these claims to insert the phrase "therapeutically an effective amount of" is suggested to obviate the above rejection.

### *Objections*

Claim 24 is objected to under 37 CFR 1.75(c) as being in improper dependent form because a multiple dependent claim should not depend on another dependent claim such as claim 22. See MPEP § 608.01(n). Correction is required.

### *Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Art Unit: 1626

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Golam M M Shameem". The signature is stylized with a large, looping initial "G" and "M".

Golam M M Shameem, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1600  
Technology Center 1

March 24, 2004